[10123/01101]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Haarala et al.
Serial No.	:	09/838,618
Filed	:	April 19, 2001
For	:	CATHETER SLIT VALVES
Group Art Unit	:	3754
Examiner	:	Buechner, Patrick M.

Mail Stop: Appeal Brief-Patent
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By: Date: February 25, 2005
Oleg F. Kaplun, (Reg. No. 45,559)

TRANSMITTAL

In support to the Notice of Appeal filed on December 28, 2004, enclosed please find an Appeal Brief for filing in the above-identified application. Please charge the credit card of Fay Kaplun & Marcin, LLP in the amount of $500.00. The Commissioner is hereby authorized to charge any additional fees to the Deposit Account of **Fay Kaplun & Marcin, LLP No.** 50-1492. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: February 25, 2005

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APPELLANTS' BRIEF ON APPEAL

This is an appeal from the Final Office Action dated August 12, 2004 finally rejecting all pending claims in the above-identified application, as further explained by the Advisory Action dated November 18, 2004.

The Final Rejection should be reversed because the rejection improperly relied on a statement of inherency and failed to establish that the reference relied upon, makes clear that the missing descriptive matter is necessarily present in the thing described in the reference and it would be so recognized by persons of ordinary skill. Thus, the cited references does not teach or suggest each and every element of the applicants' invention as claimed. In addition, the derivation of the claimed invention from the cited references following the teachings of the cited references alone would not have been obvious to the person of ordinary skill in the art at the time the invention was made. Rather, the Final Rejection is premised on an impermissible hindsight reconstruction of the prior art in light of Appellants' teachings.

The following sections of this brief are arranged in the order required by 37 C.F.R. § 1.192 and M.P.E.P. § 1206:

I. Real Party In Interest

An assignment of the above-identified application from the inventors to Scimed Life Systems, Inc. was recorded in the Patent Office at frames 252 - 255 of reel 011792 on April 13, 2001. Thus, Scimed Life Systems, Inc. is the real party in interest in this appeal.

II. Related Appeals and Interferences

A Notice of Appeal and an Appeal Brief had been previously filed in response to the Office Action dated May 6, 2003. In view of the applicants' Appeal Brief, the Examiner re-opened prosecution with new grounds for a non-final rejection prior to a decision on the merits by the Board of Patent Appeals and Interferences. *See*, the Office Action dated March 9, 2004. In response, the applicants elected to reply to the Examiner's rejection and did not request reinstatement of the prior appeal. Thus, the previous appeal has been vacated and will not have any bearing on the Board's decision in this appeal. The undersigned representative of the applicants is not aware of any other appeal or interference which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in this appeal.

III. Status of Claims

The claims pending in the case are claims 43 - 46 and 61, all of which were under rejection and on appeal.[1]

Claims 43 - 46 and 61 have been rejected under 35 U.S.C. § 102(b) as allegedly

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[1] A copy of claims 43 - 46 and 61 is attached as Appendix A.

anticipated by prior art. Furthermore, claims 43 - 46 and 61 were also rejected under 35 U.S.C. § 103(a) as allegedly obvious over certain prior art.

IV. Status of Amendments

A Response to Final Rejection dated August 12, 2004 has been considered, but was not deemed to place the application in condition for allowance. See, the Advisory Action dated November 18, 2004. The claims presently pending are as amended in the Amendment filed June 1, 2004 and re-filed on July 23, 2004 in response to a Notice of Non-Compliant Amendment.

V. Summary of Invention

The invention relates to a medical device comprising:

- an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and

- a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.

VI. Issues

Whether the medical devices of claims 43, 44 and 61 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Yoon (U.S. Patent No. 5,797,888).

Whether the medical device of claim 45 is unpatentable under 35 U.S.C. § 103(a) as obvious over Yoon in view of Phelps et al. (U.S. Patent No. 6,419,659).

Whether the medical device of claim 46 is unpatentable under 35 U.S.C. § 103(a) as obvious over Yoon in view of Desai (U.S. Patent No. 5,857,464).

VII. Grouping of Claims

Each of dependent claims 44 and 61 stands with independent claim 43. Each of dependent claims 45 and 46 stands independently of claim 43.

VIII. Argument

The substantive issues on this appeal are:

1. Whether the medical devices of claims 43, 44 and 61 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Yoon (U.S. Patent No. 5,797,888);

2. Whether the medical device of claim 45 is unpatentable under 35 U.S.C. § 103(a) as obvious over Yoon in view of Phelps et al. (U.S. Patent No. 6,419,659); and

3. Whether the medical device of claim 46 is unpatentable under 35 U.S.C. § 103(a) as obvious over Yoon in view of Desai (U.S. Patent No. 5,857,464).

It is respectfully submitted that these rejections are in error and must be reversed because the reference the Examiner relied upon for her § 102(b) rejection fails to disclose, either expressly or inherently, each and every element of the applicants' invention as recited in any of claims 43, 44 and 61 of the present invention. In addition, appellants submit that the prior art

references fail to suggest, alone or in combination, the claimed elements of a medical device as recited in either claim 44 or 45 of the present application.

It is well established that:

1. " A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. Of California, 814 F.2d 628, 631 (Fed. Cir. 1987);

2. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464(Bd. Pat. App. & Inter. 1999); and

3. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999)(citations omitted).

Furthermore, is well established that:

1. The prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991);

2. It is improper to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991);

3. Put another way, it is improper to modify a prior art reference unless the prior art suggests the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). It also is improper to pick and choose from a reference only those parts which support the rejection to the exclusion of other portions which do not. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Teachings of a reference which lead away from appellants' invention are part of the reference and must be considered. In re Mercier, 575 F.2d 1151, 1165, 185 U.S.P.Q. 774, 778 (C.C.P.A. 1975);

4. It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion or incentive to make the combination made by the inventor. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir. 1991);

5. The nature of the problem which persisted in the art and the inventor's solution are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in the art. Northern Telecom, supra., at 908 F.2d 935;

6. A combination invention is not obvious simply because each of its elements is found in different prior art references. It is improper to pick

and choose among the individual elements of different references to recreate the claimed invention. SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 886-87, 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985); and

7. Not only must the prior art suggest doing what an applicant claims, but the prior art, not applicant's disclosure, must provide both the suggestion and a reasonable expectation of success. In re Vaeck, supra., at 947 F.2d 993, 20 U.S.P.Q. 2d at 1442. Accordingly, neither "obvious to try" nor "obvious to experiment" is the standard for obviousness. Akzo NV v. E.I. dupont denemours, 810 F.2d 1148, 1 U.S.P.Q. 2d 1704, 1707 (Fed. Cir. 1987); In re Dow Chemical Co., 837 F.2d. 469, 473, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988).

The Final Rejection fails to conform to the foregoing principles. The rejection improperly relied on a statement of inherency and failed to establish that the reference relied upon, makes clear that the missing descriptive matter is necessarily present in the thing described in the reference and it would be so recognized by persons of ordinary skill. Thus, the cited references do not teach or suggest each and every element of the applicants' invention as claimed. In addition, the Final Rejection fails to establish that the references relied upon, taken separately or in combination, suggest to a person of ordinary skill in the art a medical device as appellants claim. Rather, the Final Rejection has improperly used appellants' disclosure as a

template, has selected bits and pieces from the references with the benefit of hindsight, and has disregarded evidence supporting patentability.

1. The References

The Final Rejections of claims 43, 44 and 61 are based upon the following prior art reference:

(1) Yoon (U.S. Patent No. 5,797,888).

The Final Rejection of claim 45 is based upon prior art references:

(1) Yoon (U.S. Patent No. 5,797,888); and

(2) Phelps et al. (U.S. Patent No. 6,419,659).

The Final Rejection of claim 46 is based upon prior art references:

(1) Yoon (U.S. Patent No. 5,797,888); and

(2) Desai (U.S. Patent No. 5,857,464);

As will be discussed further below, the Examiner has rejected claims 43, 44 and 61 under 35 U.S.C. § 102(b) as anticipated by Yoon, has rejected claim 45 under 35 U.S.C. §103(a) as obvious over Yoon in view of Phelps and has rejected claim 46 under 35 U.S.C. § 103(a) as obvious over Yoon in view of Desai.

a. Yoon

Yoon purports to show a catheter with a universal seal for introducing medical instruments therethrough. Yoon describes a seal biased to a closed position which is opened only when it is physically pushed outwards from the interior of the catheter. The only means Yoon described for opening the seal by pushing the pusher / instrument against sealing members of the seal and forcing the seal to flex outwardly. Yoon does not teach or suggest opening the seal in any other manner. In particular, Yoon does not teach or suggest opening a seal in response to a fluid pressure gradient. In fact, Yoon claims to act as a barrier between areas of different fluid pressure to prevent fluid flow through the cannula, regardless of pressure gradients to which it is exposed, when the pusher and/or instrument is in a retracted position and removed from the seal.

b. Phelps et al.

Phelps et al. purports to show a plaque treatment catheter including a flexible shaft with a position indicating annular band 46 adjacent its distal end. The distal end of the catheter shaft does not include a seal or a valve. Rather, Phelps et al. claims that it is engaged with a needle, which includes multiple lumens therein. Furthermore, the drawings show only a planar surface for the distal end of the needle. Neither the drawings nor the description indicate that the distal end of the needle includes a seal.

c. Desai

Desai purports to show a catheter for media injection including a tube and a valve formed at a distal end thereof. The tube is circumferentially-slitted partially along its length. Desai claims that intermediate portions of the tube deform into wings and form a cavity which allows fluids to be expelled from the interior of the catheter when acted upon by fluid pressures to permit the guidewire to pass therethrough. This valve is described as reducing the amount of contrast material required for effective angiography while reducing end-hole jets by sealing the distal end.

2. The Medical Device of Claims 43, 44 and 61 is Not Anticipated By Yoon

It is respectfully submitted that applicants' medical device as recited in claim 43 is not anticipated by Yoon, as indicated by the Examiner. The Examiner stated, in support of the rejection that Yoon discloses all of the limitations of claim 43. Specifically, the Examiner asserted that Yoon disclosed a slit that is biased closed and would inherently open due to a difference in pressure between the lumen and the ambient. See, the Office Action dated August 12, 2004, 2. In addition, the Examiner alleged that Yoon is inherently configured to allow flaps to flex into the lumen when the ambient pressure exceeds the pressure inside the lumen. See id., 2.

Claim 43 recites a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter."

The Examiner has asserted that the slit of Yoon would inherently open due to differences in fluid pressure between the lumen and the ambient. However, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464(Bd. Pat. App. & Inter. 1999). The Examiner has asserted that the above-identified characteristic is inherent, but neglected to provide a basis in fact or a technical reasoning to reasonably support her statement. Therefore, it is respectfully submitted that the Examiner has not met the requirements for relying upon the theory of inherency and thus, has not provided sufficient basis for her § 102(b) rejection.

Additionally, the Examiner is directed to the requirements for establishing inherency.

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999)(citations omitted).

It is also respectfully submitted that Yoon does not make clear that the slit would necessarily open due to differences in the fluid pressure of the lumen and fluid pressure outside the catheter.

Specifically, Yoon describes a cannula which includes a seal, "normally biased to a closed position when no instrument is passed through the cannula...." Yoon Patent, col. 4, lines 44-46. The only means discussed in Yoon's disclosure for opening the seal is by pushing a medical instrument or a pusher through the seal from the interior of the cannula in order to overcome the closing bias of the seal. See id., col. 6, lines 57-62. The seal opens to accommodate and substantially conform to the shape of the instrument, but returns to a closed position upon removal of the instrument from the seal. See id., col. 4, lines 58-62. Similarly, the seal also opens to substantially conform to the exterior of a tubular pusher. See id., col. 7, lines 4-9. However, the seal is biased to a closed position and "once the pusher has returned to the retracted position, the seal will no longer be held in an open position and will be free to move to a sealing position with seal members urged toward the closed position...." Id., col. 7, lines 31-34 (citations omitted). Yoon makes no reference to a compound slit that opens in response to the difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. Rather, as discussed above, the Yoon reference makes it clear that the seal is to remain closed at all times when no pusher or instrument is pushed therethrough to force the sealing members to an open position. Opening a slit in response to a difference of fluid pressures between the interior and the exterior of the catheter is unrelated to and does not necessarily flow from opening a seal by overcoming the closing bias with a pusher or a medical instrument. Specifically, at the pressures to which such medical devices are exposed, this seal is designed to remain closed. Of

course the seal eventually would open if the pressure applied thereto were continually increased. However, the solid walls of the catheter would also eventually open under these conditions. It is respectfully submitted that such strained interpretations are not indicative of the understanding which would be developed by a person skilled in the art upon reading Yoon. Thus, appellants respectfully submit that there is no inherent disclosure of a compound slit opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.

The present invention as disclosed by claim 43 refers to a medical device including a compound slit biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. The compound slit of the appellants' invention opens and permits fluid flow through the catheter in response to an increased pressure differential between the lumen and the external environment. For example, as described in the specification, in an infusion mode, "the pressure within the lumen 228 is increased with respect to the environmental pressure, thereby causing the catheter walls 227 adjacent the slit 222 to begin to move apart, allowing infusion of fluid to the external environment." Specification, ¶[0078]. Furthermore, the catheter may alternatively configure to an aspiration mode, where "[a]s the lumen pressure decrease[s] with respect to the environmental pressure, one side of the slit valve 222 yields, or flexes inwardly, to allow fluid to enter the catheter lumen 228." Id., ¶[0078]. As would be understood by one of ordinary skill in the art, the slit described by the appellants' application may open to permit fluid flow without placing a physical structure (i.e., a pusher or a medical instrument) through the slit to overcome the closing bias of the sealing members.

Applicants respectfully submit that the Examiner's reading of Yoon is directly contradictory to the teachings contained therein. In particular, Yoon claims that fluid flow between the interior of the cannula and the exterior environment is undesirable and prohibited by the seal. See Yoon Patent, col. 10, lines 3-6. Yoon makes clear that the seal prevents fluid flow through the cannula; particularly when the sealing members are not forced to an open configuration by the insertion of a pusher or a medical instrument. See id., col. 10, lines 10-14.

More specifically, "[t]he seal can have any configuration to prevent fluid flow through the cannula prior to the introduction of instruments through the cannula, after the instruments are withdrawn from the cannula and/or while the instruments are in place." Id., col. 9, lines 53-57. One of ordinary skill in the art would understand that fluids generally flow from an area of high concentration / pressure to an area of low concentration / pressure. Accordingly, because Yoon's seal is designed to prevent fluid flow across the seal, the seal must serve as a barrier between two areas of different fluid pressures. Therefore, appellants respectfully submit that Yoon does not disclose a seal that succumbs to fluid pressure gradients and opens in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.

The Yoon reference further illustrates that the seal is not equivalent to the compound slit which opens in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter, as recited by claim 43 of the applicants' invention. Specifically, Yoon describes the use of a plurality of spring wires or stiffeners to maintain the seal in a closed position. See id., col. 4, lines 62-67 and col. 5, lines 1-4. Use of the spring wires in the seal would prevent anything other than a pusher or a medical instrument from overcoming the closing bias and forcing open the seal. It is respectfully submitted that there is no disclosure that would lead one to conclude that the resilient force of the spring wires and other structures biasing the slits closed would open under the influence of any fluid pressure gradients as are encountered in the anatomical environments to which medical devices, such as the present invention, are exposed.

In its specification, Yoon discussed the use of a distensible or inflatable membrane as disclosed in U.S. Patent Application Serial No. 09/383,520 ('520 Application), which is now abandoned. See Yoon Patent, col. 11, lines 4-6. Furthermore, Yoon incorporated the disclosure of the abandoned '520 application by reference. See id., col. 11, lines 5-8. U.S. Patent No. 5,752,970 to Yoon ('970 Patent) is a continuation thereof and thus, shares the same disclosure as the '520 application. In the '970 patent, an expandable membrane, the same as that incorporated by Yoon, may be used to seal the distal end. Thus, Yoon includes the membrane as

an element of the seal. Therefore, characterizations of the seal disclosed by the '970 patent applies to Yoon as well. The disclosure of the '970 patent further brings to light that the seal recited by Yoon does not permit opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. In fact, the disclosure of the '970 patent expressly states to the contrary that "[t]he valves are preferably configured as one-way valves such that **external forces and pressures exerted on the valves from outside the cannula will not cause the valves to open.**" '970 Patent, col. 7, lines 59-62 (emphasis added). Therefore, in view of the disclosure incorporated by reference, Yoon clearly teaches away from a compound slit opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.

The Examiner asserts that "[t]he slit of Yoon is also configured to inherently allow the flaps to flex into the lumen when the ambient pressure exceeds the pressure inside the lumen." Appellants respectfully disagree with the Examiner's statement. The seal in Yoon never opens in response to an inward force and only opens outwardly a result of being physically pushed by the pusher or the instrument. In addition, the seal acts to prevent all fluid flow back into the cannula. One of ordinary skill in the art would ascertain that the pusher or instrument exerts only an outward physical force against the seal from the interior of the cannula and that the seal does not open in response to inward forces, such as fluid flow back into the cannula. Consequently, it is respectfully submitted that that the device of Yoon teaches away from the configuration claimed by the applicants. Appellants further submit that Yoon does not teach a slit that opens in response to a pressure gradient, because such a slit would respond to both inward and outward forces.

The appellants have shown above that Yoon does not contemplate opening the seal in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. In fact, Yoon has repeatedly taught away from a seal that responds to change in fluid pressure. In addition, Yoon has also taught away from the configuration of the seal as claimed by the applicants. Accordingly, it is respectfully submitted that Yoon does not

make clear that the description of a slit that is biased closed and opens due to a difference in pressure between the lumen and the ambient as well as a slit configured to allow flaps to flex into the lumen when the ambient pressure exceeds the pressure inside the lumen are necessarily present in Yoon's disclosure and that it would be so recognized by persons of ordinary skill. Thus, the appellants respectfully submit that these elements are not inherent within the Yoon reference.

" A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. Of California, 814 F.2d 628, 631 (Fed. Cir. 1987). It is respectfully submitted that Yoon does not show or suggest each and every element of a medical device comprising an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter as recited in amended claim 43.

Accordingly, applicants respectfully submit that Yoon does not disclose, either expressly or inherently, each and every element of independent claim 43 and that this rejection should be withdrawn. Because claims 44 and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable for the same reasons as indicated above.

3. The Medical Device of Claim 45 is Not Obvious Over Yoon in View of Phelps et al.

It is respectfully submitted that the appellants' medical device as recited in claim 45, is not obvious over Yoon in view of Phelps et al. for substantially the same reasons stated

above in regard to claims 43, 44 and 61.

The Examiner stated, in support of the rejection that Yoon as described above shows a device substantially as claimed except for the element of a collar disposed adjacent to the distal end of the catheter, but that Phelps et al. discloses a collar disposed adjacent the catheter's distal-most end. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above-mentioned prior art and that "[d]oing so would provide an attending physician with a means for determining the location of the catheter by magnetic or electromagnetic means." *See* Office Action dated August 12, 2004, 3 (citations omitted).

It is respectfully submitted that claim 45 is allowable for the at least the same reasons stated above in regard to claims 43, 44 and 61, and that Phelps et al. fails to cure the noted defects.

4. The Medical Device of Claim 46 is Not Obvious Over Yoon in View of Desai

It is respectfully submitted that the appellants' medical device as recited in claim 46, is not obvious over Yoon in view of Desai for substantially the same reasons stated above in regard to claims 43, 44 and 61.

The Examiner stated, in support of the rejection that Yoon as described above shows a device substantially as claimed except for the element of a tricuspid flap configuration, but Desai discloses a valve with three flaps. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above-mentioned prior art and that "it would be a simple matter of choosing a design for an end valve from existing designs known in the art, when each design would perform equally well." *See* Office Action dated August 12, 2004, 3.

In addition, applicants respectfully submit that neither of the cited references provides any suggestion, incentive or motivation for the combination as suggested by the Examiner. "Multiple cited prior art references must suggest the desirability of being combined and the reference must be viewed without the benefit of hindsight afforded to the disclosure."(emphasis added) In re Paulsen, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Applicants respectfully submit that *there is no motivation or incentive to combine* Yoon with Desai to allegedly teach or suggest Applicants' claimed invention.

As stated by the Federal Circuit, "the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure." See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

Yoon teaches away from the proposed combination. Desai discloses a valve designed to open when acted upon by the force of fluid pressure to permit the guidewire to pass therethrough. Contrary to Desai, as discussed above, Yoon's seal opens only when a pusher or an instrument is physically pushed against the seal and overcoming the closing bias. The disclosure of Yoon makes it clear that seal serves to prevent fluid flow and will not succumb to fluid pressure.

As described above, Yoon prohibits fluid flow through the catheter even when opened by a pusher or instrument extending through the sealing members by tightly sealing around the pusher or instrument. Withdrawing the guildwires will seal the valve at the distal end of Desai's catheter as well. However, contrary to Yoon, Desai continues to evacuate liquids from the interior of the catheter to a cavity formed by intermediate portions of a slitted catheter tube, even subsequent to closing the distal valve. See Desai Patent, col. 5, lines 55-58. As described above, Desai does not restrict fluid flow in the same manner. Thus, since Yoon and Desai describe contradictory devices, it is respectfully submitted that neither of these references provides any suggestion, incentive or motivation for the combination and that this combination is an improper hindsight reconstruction.

It is respectfully submitted that neither Yoon nor Desai shows or suggests a medical device comprising an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface, wherein the compound slit is a tricuspid slit as recited in claim 46 .

Applicants respectfully submitted that claim 46 is allowable for the at least the same reasons stated above in regard to claims 43, 44 and 61, and that Desai fails to cure the noted defects. Furthermore, it is respectfully submitted that claim 46 is neither shown nor suggested by the above-cited references either taken alone or in combination and that this rejection should be withdrawn.

IX. Conclusion

It is respectfully submitted that appellants have demonstrated that the subject matter of independent claim 43 and those dependent therefrom (claims 44 and 61) are not anticipated by the cited prior art. In addition, appellants further submit that claims 45 and 46 are not obvious in light of the cited art, taken taken alone or in combination. Thus, it is respectfully requested that the Examiner's final rejection of claims 43 - 46 and 61 be reversed and all appealed claims found patentable.

Respectfully submitted,

Date: February 25, 2005

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APPENDIX A – APPEALED CLAIMS

43. A medical device comprising:

an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and

a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.

44. A medical device according to claim 43, wherein the compound slit is disposed on a distal end of the elongate catheter.

45. A medical device according to claim 44, further comprising a collar disposed at the distal end of the catheter.

46. A medical device according to claim 43, wherein the compound slit is a tricuspid slit.

61. A medical device according to claim 43, wherein the compound slit is configured so that, when the fluid pressure within the lumen exceeds the fluid pressure outside the catheter by a first predetermined amount, flaps of the hemispherical portion formed by the compound slit flex outward away from a longitudinal axis of the catheter to allow fluid within the lumen to exit and when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen.